
Q. What is an Emergency Use Authorization?
A: In certain types of emergencies, the HHS Secretary may issue a determination and declaration under the Food Drug and Cosmetic Act that permits FDA to issue emergency use authorizations (EUAs) to facilitate access to medical countermeasures (drugs, biologics, vaccines, and devices) that can be used to diagnose, treat or prevent a serious disease or condition in a public health emergency. Products authorized for use in this way may not be approved by FDA for any use, or they may be approved for other uses but not for the emergency use. FDA decides whether the use of the product is likely to be more helpful than harmful for the emergency use; i.e., the agency determines that the known and potential benefits of the medical products for their intended uses outweigh their known and potential risks. This authorization is reserved for emergency situations and is NOT the same as FDA approval or licensure.

Q. What does this EUA allow?
A. The EUA allows remdesivir, manufactured by Gilead, to be distributed and used by licensed healthcare providers to treat adults and children hospitalized with severe COVID-19. Severe COVID-19 is defined as patients with an oxygen saturation (SpO2) ≤ 94% on room air or requiring supplemental oxygen or requiring mechanical ventilation or requiring extracorporeal membrane oxygenation (ECMO), a heart-lung bypass machine.

Q. Is remdesivir approved by the FDA to treat COVID-19?
A. No. Remdesivir is an investigational antiviral drug. It is not currently FDA-approved to treat or prevent any diseases, including COVID-19.

Q. Is there data showing remdesivir might benefit patients with COVID-19?
A. In vitro (laboratory) testing of remdesivir demonstrated it is active against SARS-CoV-2 (the virus causing COVID-19). Preliminary results from a placebo-controlled clinical trial of remdesivir by the National Institute for Allergy and Infectious Diseases suggested that patients taking remdesivir experienced faster time to recovery as compared to patients taking a placebo. Preliminary results from a Phase 3 trial evaluating 5-day and 10-day dosing durations of remdesivir in hospitalized patients with severe COVID-19 disease, but most of whom were not receiving mechanical ventilation or ECMO at baseline, reported that patients receiving a 10-day treatment course achieved similar improvement as those taking a 5-day treatment course. The safety and efficacy of remdesivir for the treatment of COVID-19 are being evaluated in multiple ongoing clinical trials.

Because remdesivir may possibly help very sick patients, FDA is allowing this drug to be provided to hospitalized patients with severe COVID-19 under an EUA issued May 1, 2020. Under the EUA, health care providers and patients are provided with information about the risks of remdesivir. However, final data from clinical trials included in an FDA application are necessary for us to determine whether the drug is safe and effective in treating or preventing COVID-19.

Q. Are there clinical trials underway evaluating remdesivir for COVID-19?
A. Yes. Clinical trials are completing to determine if remdesivir can benefit patients with COVID-19 infection. Additional trials may be planned in special populations such as patients with kidney problems or use of remdesivir with other drugs to treat COVID-19.

The EUA includes a fact sheet for health care providers that contains additional information about results from clinical trials for remdesivir.

Q. Are there side effects of remdesivir?
A. Possible side effects of remdesivir are:

- Infusion-related reactions. Infusion-related reactions have been seen during a remdesivir infusion or around the time remdesivir was given. Signs and symptoms of infusion-related reactions may include: low blood pressure, nausea, vomiting, sweating, and shivering.
- Increases in levels of liver enzymes, seen in abnormal liver blood tests. Increases in levels of liver enzymes have been seen in people who have received remdesivir, which may be a sign of inflammation or damage to cells in the liver.

These are not all the possible side effects of remdesivir. Remdesivir is still being studied so it is possible that all of the risks are not known at this time.

Q. Is there a requirement for providers to report side effects as part of the EUA?
A. Yes. As part of the EUA, FDA is requiring health care providers who prescribe remdesivir to report all medication errors and serious adverse events considered to be potentially related to remdesivir through FDA’s MedWatch Adverse Event Reporting program. Providers can complete and submit the report online; or download and complete the form, then submit it via fax at 1-800-FDA-0178. This requirement is outlined in the EUA’s health care provider fact sheet. FDA MedWatch forms should also be provided to Gilead.

Q. How can remdesivir be obtained for use under the EUA?
A. The U.S. government will coordinate the donation and distribution of remdesivir to hospitals in cities most heavily impacted by COVID-19. Given the severity of illness of patients appropriate for remdesivir treatment and the limited availability of drug supply, hospitals with intensive care units and other hospitals that the government deems most in need will receive priority in the distribution of remdesivir. Gilead is working with the U.S. government on the logistics of remdesivir distribution and will provide more information when the company begins shipping the drug under the EUA.

While we await the full implementation of the remdesivir EUA, remdesivir remains available through the following mechanisms:

1) Expanded Access Protocol (EAP)

2) Emergency investigational new drug applications (EINDs) for pregnant women and children

3) Gilead’s Randomized Controlled Trials (Part B is still enrolling for both trials) –
   - Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Severe Coronavirus Disease (COVID-19) and
Study to Evaluate the Safety and Antiviral Activity of Remdesivir (GS-5734™) in Participants With Moderate Coronavirus Disease (COVID-19) Compared to Standard of Care Treatment